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III. 510(K) Summary

SUBMITTED BY:

Globus Medical Inc.
303 Schell Lane
Phoenixville, PA 19460
(610) 415-9000 x218
Contact: Kelly J. Baker

DATE PREPARED:

February 15, 2005

DEVICE NAME:

PROTEX™ CT Cervicothoracic Spinal System

CLASSIFICATION:

Per CFR as follows:
21 CFR §888.3050 Spinal Interlaminal Fixation Orthosis
21 CFR §888.3070 Pedicle Screw Spinal System
Product codes KWP and MNI.
Panel code is 87.
Device classification Class II.

PREDICATE DEVICES:

Danek Vertex (K003780, K042524)
Depuy Summit (K002733, K041203)
Howmedica Osteonics (Stryker) Oasys (K032394)
Synthes Cervifix/Axon (K023675)

DEVICE DESCRIPTION:

The PROTEX™ CT Spinal System consists of rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, and occipital clamps. The implants are composed of titanium alloy.

INTENDED USE:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the PROTEX™ CT Spinal System is indicated for: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, atlanto/axial

fracture with instability, occipitocervical dislocation, revision of previous cervical spine surgery, and tumors.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine. Occipital bone screws are limited to occipital fixation; they are not intended for fixation of the posterior cervical spine.

The PROTEX™ CT System can also be linked to titanium rod systems ranging in diameter from 3.7mm to 6.5mm, including the PROTEX™ System, using parallel connectors.

PERFORMANCE DATA:

Mechanical testing was conducted to evaluate performance as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2005

Kelly Baker, Ph.D.
Project Manager, Regulatory Affairs
Globus Medical, Inc.
303 Schell Lane
Phoenixville, Pennsylvania 19460

Re: K050391
Trade/Device Name: PROTEX™ CT Cervicothoracic Spinal System
Regulation Number: 21 CFR 888.3070 and 21 CFR 888.3050
Regulation Name: Pedicle screw spinal system and Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP and MNI
Dated: July 8, 2005
Received: July 11, 2005

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Indications for Use Statement

510(k) Number: K050391

Device Name: PROTEX™ CT Cervicothoracic Spinal System

Indications:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the PROTEX™ CT Spinal System is indicated for: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, atlanto/axial fracture with instability, occipitocervical dislocation, revision of previous cervical spine surgery, and tumors.

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Prescription Use __X__ OR Over-The-Counter Use____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(510(k) Number) K050391